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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
RANSAL,G	
ART UNIT	PAPER NUMBER
1642	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/273230	Hudziak et al
Examiner	**Group Art Unit**
Geeta Bansal	1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3/5/2001.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 42-49 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☒ Claim(s) 42-49 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

DETAILED ACTION

1. Applicant's response of March 5, 2001 (Papers No: 9) is acknowledged. No claim has been amended. Claims 42-49 are being examined.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 42-49 as set out in the previous office action under 35 U.S.C. 112, 1st paragraph is maintained. Applicant's arguments have been considered but they are not persuasive. Applicant argues that the specification describes a formulation which is particularly adapted for subcutaneous administration. Applicant further states that the specification describes how to overcome the problems associated with obtaining high antibody concentrations in the formulation thus allowing for subcutaneous administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. The claims are drawn to a method of treatment of patients having cancers that over express HER-2 by administering a generic antibody to HER-2. The claims are also directed to a method of treating any patient having any cancer by administering an antibody against the HER2 receptor. There is no teaching disclosed in the specification of treating or inhibiting the growth of tumor cells. The specification discloses methods of making different formulations of an antiHER-2 antibody and an anti IgE antibody. There are a number of examples to support the various formulations for providing stability to a preparation of antibodies, different stabilizing agents used, different reconstitution experiments, but no guidance as to how to set about treating a mammal with a cancer overexpression of HER-2. One of skill in the art would be forced into undue experimentation to practice the claimed invention because the specification does not provide a teaching as to what properties of an anti

HER2 MAb (monoclonal antibody) would have therapeutic efficacy, whether in the form of a conjugate or alone, how to set about obtaining a therapeutically effective antibody. The disclosure has no connection with the claimed subject matter, but merely provides methods and guidance to produce an antibody formulation. Claims drawn to treating a cancer are not enabled by the disclosure. Applicant argues that the claimed invention has been documented by the marketing approval to a humanized MAb HERCEPTIN®. However, the claims are drawn to a method of treatment that is not the subject matter of this Application. It appears that a specific formulation of a specific antibody is being argued in support of the claims which is not described in the specification. As stated earlier the specification is totally focussed on an optimal formulation, which has no support in the specification as to superior treatment or unexpectedly better results.

An effective therapeutic protocol for the treatment or prevention of the formation of a tumor is subject to a number of factors which enter the picture beyond simply the specific binding of an antibody to the tumor cell line or the derived antigen. Demonstrating tumor antigen specificity in vitro cannot alone support the predictability of the method for prevention of or treating said tumor growth through administration of either the antibody. The establishment and growth of a tumor is subject to variables beyond antigen specificity. The ability of a host to suppress and thereby prevent the tumor from establishing itself will vary depending upon factors such as the condition of the host, the type of tumor (rapidly proliferating or slowly proliferating) and the tumor burden. No guidance is provided for all of these points as set forth above. It appears that Applicant is claiming treating tumors that overexpress HER-2 with an antibody formulation wherein the antibody binds to HER-2 and argues that MAbs other than HER-2 have been described in the enumerated references (see page 3, 2nd paragraph of Applicant's response). However, it is noted that several antibodies were demonstrated to bind in vitro to transfected tumor cells and that the invivo experiments with 2H11 and 3E8 also were directed to inhibiting transfected tumor cells and not spontaneously occurring cancers overexpressing HER-2. The

reference of Combs et al is noted. This reference can be considered to provide support for a very specific MAb with a very specific formulation characteristics, and as a formulation for subcutaneous use in treatment of cancers overexpressing HER-2. The specification does not enable the claims drawn to treatment methods.

4. The missing IDS is being sent herewith, after consideration.

5. No claim is allowed.

6. ~~No claims are allowed~~. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette,

1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bansal

GEETHA P. BANSAL
PRIMARY EXAMINER

May 15, 2001